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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/544,150  | 08/01/2005  | Francis X. Smith     | 3009040 US01        | 6441             |
| 44331 7590 06/10/2010<br>HISCOCK & BARCLAY, LLP<br>2000 HSBC PLAZA<br>100 Chestnut Street<br>ROCHESTER, NY 14604-2404 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| BASQUILL, SEAN M  |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1612  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
| 06/10/2010  |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/544,150

**Applicant(s)**

SMITH, FRANCIS X.

**Examiner**

Sean Basquill

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2010.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 11 and 14 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-8, 11 and 14 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SI.08)  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_  
Paper No(s)/Mail Date: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 2, , and 14 have been amended, and Claims 9, 10, 12, and 13 cancelled. Claims 1-8, 11, and 14 are presented for examination.

### ***Previous Rejections***

2. Applicants' arguments, filed 28 April 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-4, 7-8, 11, and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,817,277 ("Mowrey-McKee") in view of British Patent Specification Publication GB 1,431,841 ("Evans"), as put forth in the office action dated 28 October 2009.

Applicants arguments have been fully considered and are deemed unpersuasive. As put forth previously, the claim language "a contact lens solution" of the instant claims recites an intended use of the composition as fully described thereafter, requiring only that the solution be compatible with contact lenses, which the examiner asserts the compositions described by the

art, as ophthalmically acceptable and useful compositions, are. Moreover, the compositions disclosed by Mowrey-McKee are in fact described as, in addition to being useful carriers for ophthalmic active agents, useful as contact lens disinfecting solutions. Assuming *arguendo* that the phrase “contact lens solution” is in fact an affirmative limitation of the claim, it is a limitation which the art applied in the instant rejection discloses. Moreover, as both Mowrey-McKee and Evans describe ophthalmic compositions useful for treating ocular disorders or promoting the health of the eye, they represent teachings of analogous art. As such, the instant claims define a rearrangement of elements individually known in the prior art, with each performing as an artisan possessing ordinary skill would expect. *See KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraid v. A.G. Pro*, 425 U.S. 273, 282 (1976)) (indicating that “when the question is whether a patent claiming the combination of elements of prior art is obvious,” the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions”).

Furthermore, applicants allegations of unexpected results, specifically an improvement in antimicrobial efficacy when B vitamins are included in ophthalmic compositions, are unsupported by the evidence of record. As a threshold matter, the only evidence of record tending to support such a claim, the data presented in paragraphs 28 and 29 of the specification as originally filed, cannot stand for the proposition that the presence of the claimed B vitamins improves antimicrobial efficacy. The first issue is that only one B vitamin, dexpanthenol, has been tested at all. This cannot support an assertion that any of the B vitamins as claimed will improve antimicrobial efficacy. Second, and more critically, the experimental data fails to control for the presence or absence of only the B vitamin in assessing antimicrobial efficacy; in

addition to lacking the B vitamin, the comparator composition also lacks the buffer Bis-tris propane in a concentration of 0.2%. It is therefore scientifically impossible to determine with any degree of reliability that the difference in antimicrobial efficacy is in fact related to the presence or absence of the B vitamins as asserted by the applicants. Finally, applicants have offered neither argument nor data to support the required contention that such improvement in antimicrobial efficacy is, in fact, unexpected as is required to overcome a *prima facie* case of obviousness. MPEP § 716, *et seq.*

In sum, all of the affirmative claim limitations as currently presented have been met, and a rationale provided for their combination. Data alluded to by applicants is legally and scientifically incapable of overcoming the examiner's *prima facie* case of obviousness; as a result the rejections of record shall stand.

4. Claims 1-8, 11, and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mowrey-McKee as modified by Evans as applied to claims 1-4, 7-8, 11, and 14, above, and further in view of U.S. Patent 6,162,393 ("De Bruij"), as put forth in the office action dated 28 October 2009.

Applicants arguments have been fully considered and are deemed unpersuasive for the reasons put forth above.

***Double Patenting***

5. Claim 10 stands provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 11 of copending Application No. 11/620,318. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

6. Claims 1-8, 11, and 14 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11/620,318. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons put forth in the previous action. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

***Conclusion***

No Claims stand allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill

Application/Control Number: 10/544,150

Page 7

Art Unit: 1612

Art Unit 1612

/Jeffrey S. Lundgren/

Primary Examiner, Art Unit 1639